



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

May 08, 2008

DP BARCODE: D350504

MRID: 470276-00, 470276-01, 470276-02, 470276-04,
470276-06, 470276-07, 470607-01, & 473696-01

SUBJECT: ChitoSanté™ MUP

REG. NO. OR FILE SYMBOL: 75100-E

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use ☒ OR End-use Product ☐

INGREDIENTS (PC Codes) Chitosan (128930)

CAS Number: (9012-76-4)

TEST LAB:

SUBMITTER: VA & G Bioscience, Inc.

GUIDELINE: 830 Guidelines.

COMMODITIES: Formulation

REVIEWER: Juan F. Negrón

ORGANIZATION: AD.

APPROVER: Karen P. Hicks

APPROVED DATE: 05/08/08

COMMENT:




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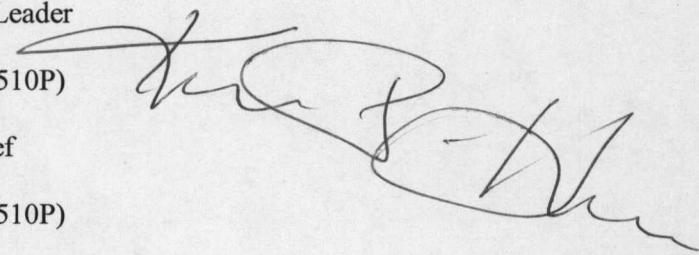
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MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 75100-E

From: Juan F. Negrón, Chemist 
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P) 

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward / Renae Whitaker
PM Team 34

APPLICANT: VA & G Bioscience, Inc.

Action code: A532

Due date: 07/30/08

Product Formulation
Active Ingredient(s)

Chitosan

% by wt.
99

BACKGROUND:

On behalf of the registrant, VA & G Bioscience, Inc., the consultant, Health & Environmental Horizons, LTD, is submitting a new project for review. The consultant sent a letter indicating a description of source of chitosan in which occurs naturally in a variety of crustaceans. The registrant is doing a me-too, EPA Reg # 81446-1, since the product is similar to the new product. The integrated manufacturing-use product, ChitoSanté™ MUP, is for manufacturing/formulating use only. The active ingredient (AI) inhibits the growth of non-health related organisms such as bacteria, mold, mildew and fungus. The Product Chemistry Reviewer has received the following documents:

- Letters, dated 12/29/06 MRID # 470276-00, & 03/08/08.
- Labels dated 03/08/08, & 05/01/08 (pin punched as of 05/07/08).
- Application for pesticide for registration, dated 03/08/08.
- Certification with respect to citation of data, dated 03/08/08.
- Data matrix, dated 03/08/08.
- Study titled "Product Identification and Disclosure of Ingredients; Certified Limits ChitoSanté MUP" (page 1 of 6).
- Study titled "Product Identification and Disclosure of Ingredients; ChitoSanté" (CBI page 1 of 3).
- Study titled "Description of Beginning Materials and Manufacturing Process ChitoSanté MUP" (Page 1 of 2).
- Study titled "Preliminary Analysis of 5 Batches ChitoSanté MUP" (Page 1 of 2).
- Study titled "Enforcement and Analytical Method ChitoSanté MUP" (Page 1 of 2).
- Waiver request for product chemistry group "B" data requirements for a manufacturing use product.
- Study titled "Product Chemistry, Group B."
- Registrant submitted some literature references supporting product properties data waivers.
- Study titled "Preliminary Analysis of 5 Batches Technical Chitosan" (Page 1 of 10). MRID # 470276-04.
- Study titled "Discussion of the Formation of Impurities" (Page 1 of 10). MRID # 470607-01.
- Study titled "Description of Beginning Materials and Manufacturing Process Technical Chitosan" (Page 1 of 23)." MRID # 470276-02.
- Study titled "Physical and Chemical Characteristics: physical state, pH, and density (Technical Chitosan)" (Page 1 of 8)." MRID # 470276-07.
- MSDS for sodium hydroxide, hydrochloric acid, & acetic acid.
- Study titled "Enforcement and Analytical Method Technical Chitosan" (Page 1 of 9)." MRID # 470276-06.
- Study titled "Product Identification and Disclosure of Ingredients Bac-Shield EPA Reg. # 81446-1" (Page 13 of 14)." MRID # 470276-01.
- Study titled "Description of Technical Chitosan" (Page 4 of 14)." MRID # 470276-02.
- Study titled "Product Identification and Disclosure of Ingredients; Certified Limits ChitoSanté MUP" (Page 1 of 6)." MRID # 473696-01.

- Confidential Statements of Formula (CSFs), dated 03/08/08, & 05/01/08, for the basic formulation.

FINDINGS:

1. The registrant indicated in a study that the 830.1600, 830.1620, & 830.1650 guidelines reference to MRID # 470276-(01, 02, 04, and 06). These MRID numbers reference to an EPA Reg # 81446-1 who has a concentration of 6% for the active ingredient. (not acceptable)
2. The registrant is using five batches of analysis (MRID # 470276-04) that is not similar concentration and has been reviewed indicating a data gap for the 830.1700 guideline. However, the registrant updated the five batches of analysis and has been provided to the Agency.
3. The registrant reference to a document (MRID # 470607-01) that describe the impurities. However, it does not mention any impurities instead contain manufacturing process details. The registrant provided the information to the Agency.
4. The registrant indicated that the manufacturing process is the same as the EPA Reg # 81446-1. However, this process targets a final concentration of 88% to 92%, and the registrant has not indicated how to achieve the 100% as per label. The registrant updated the information and the new target is 99% (See new label).
5. The registrant is doing a me-too using an EPA Reg # 81446-(1 & 2). None of these products are similar to "ChitoSanté™ MUP."
6. The CSF, dated 03/08/08, for the basic formulation is obsolete.
7. The CSF, dated 05/01/08, for the basic formulation is revised.
8. The CSF and the label have the same nominal.
9. The propose label dated 03/08/08 is obsolete. See new label dated 05/01/08 (pin punched as of 05/07/08).

CONCLUSION:

The product chemistry package is completed and is acceptable. The CSF, dated 05/01/08, for the basic formulation is acceptable. The original documentation had some deficiencies that were resolved during the product chemistry review.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system ☐
- Are all TGAs used registered? Yes ☐ No ☐
- Integrated formulation system ☒
- If "ME-TOO," specify EPA Reg. No. of existing product: EPA Reg #
81446-1 & 2

b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.

Yes ☐ No ☐

Note: This product is not intended for food use.

c. Physical state of product: Solid

d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes ☐ No ☐

e. The NCs and CLs are acceptable.

Yes ☒ No ☐

f. Active ingredient(s)	<u>NC</u>	<u>LCL</u>	<u>UCL</u>
	(%)	(%)	(%)
Chitosan	99	97	103

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes ☐ No ☐ Not applicable ☒
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes ☐ No ☐ Not applicable ☒

II PRODUCT LABEL

- a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ [X]
No ☐ []
- b. The formula contains one of the following:
- | | | |
|--|----------------------------------|--|
| • 10% or more of a petroleum distillate: | Yes <input type="checkbox"/> [] | No <input checked="" type="checkbox"/> [X] |
| • 1.0% or more of methyl alcohol: | Yes <input type="checkbox"/> [] | No <input checked="" type="checkbox"/> [X] |
| • sodium nitrite at any level: | Yes <input type="checkbox"/> [] | No <input checked="" type="checkbox"/> [X] |
| • a toxic List 1 inert at any level: | Yes <input type="checkbox"/> [] | No <input checked="" type="checkbox"/> [X] |
| • arsenic in any form: | Yes <input type="checkbox"/> [] | No <input checked="" type="checkbox"/> [X] |
- c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes ☐ [] No ☐ [] Not applicable ☒ [X]
- d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes ☐ [] No ☐ [] Not applicable ☒ [X]
- e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes ☒ [X] No ☐ []
- f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes ☐ [] No ☒ [X]

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	
830.1600 Description of Materials	A	
830.1620 Production Process ²	A	
830.1650 Formulation Process ³	A	
830.1670 Formation of Impurities ⁴	A	
830.1700 Preliminary Analysis ⁵	A	
830.1750 Certified Limits ⁶	A	
830.1800 Analytical Method ⁷	A	
830.1900 Submittal of Samples	[Samples are to be provided on a case-by-case for manufacturing-use products.]	

Explanation: A=acceptable; NR=not Required.

¹See Confidential Appendix A for additional information

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	Varies from white to pale tan, yellow or gray	
830.6303 Physical State	A	Solid	
830.6304 Odor	A	Faint sea-side odor	
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	Not required for MUP.	
830.6314 Oxidation/Reduction	A	Does not contain REDOX agent.	
830.6315 Flammability/Flame Extension	A	Solid and it is not flammable.	
830.6316 Explodability	A	Not explosive.	
830.6317 Storage Stability	W	See MRID #44292301, 46248901.	
830.6319 Miscibility ¹	A	Not to be diluted with petroleum solvents	
830.6320 Corrosion Characteristics	A	No reaction to the package.	
830.6321 Dielectric Breakdown Voltage	NR	Not required for MUP.	
830.7000 pH ²	A	6.5-7.5 in water. 4.57 in 1% acetic acid.	
830.7050 UV/Visible Absorption	NR	Not required for MUP.	
830.7100 Viscosity	A	Solid.	
830.7200 Melting Point/Melting Range	NR	Not required for MUP.	
830.7220 Boiling Point/Boiling Range	NR	Not required for MUP.	
830.7300 Density/Relative Density/Bulk Density	A	1.05 g/cm ³	
830.7370 Dissociation Constants in Water	NR	Not required for MUP.	
830. (7550, 7560, 7570) Partition Coefficient	NR	Not required for MUP.	
830. (7840, 7860) Water Solubility	NR	Not required for MUP.	
830.7950 Vapor Pressure	NR	Not required for MUP.	

Explanation: A=acceptable; NR=not required.